DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

January 12, 2015

Re: K143223
Trade/Device Name: CGBA-032A, Aquilion™ PRIME Self-Propelled Scan Base Kit for IVR-CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 12, 2014
Received: November 13, 2014

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Reset Form

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143223

Device Name

CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT

Indications for Use *(Describe)*

Optional movable gantry base unit for use with an Aquilion PRIME system to support longitudinal movement and allow acquisition of images in the z-direction (z-axis).

Note: When installed with the movable gantry base unit, Aquilion PRIME can be used with the INFX-8000C system in the same room.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TOSHIBA
Leading Innovation

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

510(k) SUMMARY

SUBMITTER'S NAME:
Toshiba America Medical Systems, Inc.

1. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA 92780-2068

2. **ESTABLISHMENT REGISTRATION:**
   2020563

3. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

4. **Date Prepared:**
   November 7th, 2014

5. **TRADE NAME(S):**
   CGBA-032A, Aquilion™ PRIME Self-Propelled Scan Base Kit for IVR-CT

6. **COMMON NAME:**
   Computed Tomography X-Ray System

7. **DEVICE CLASSIFICATION:**
   Class II
   21 CFR 892.1750 - Computed Tomography X-Ray System

8. **PRODUCT CODE / DESCRIPTION:**
   JAK – System, X-Ray, Tomography, Computed

9. **PERFORMANCE STANDARD:**
   This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

10. **PREDICATE DEVICES:**

Product	Marketed by	510(k) Number	Clearance Date	RTA Acceptance Date
Aquilion™ ONE Vision Self-Propelled Scan Base for IVR CT	Toshiba America Medical Systems	K134025	September 5, 2014	N/A
Aquilion™ PRIME	Toshiba America Medical Systems	K141741	N/A	July 11, 2014
Infinix™ INFX-8000C	Toshiba America Medical Systems	K113052	November 22, 2011	N/A

11. REASON FOR SUBMISSION:

Modification of a cleared device.

The purpose of this submission is to seek market clearance for CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT. This device is an optional kit intended to be used on an Aquilion PRIME / INFX-8000C based IVR-CT system. It is attached to the CT gantry to support longitudinal movement and allow image acquisition in the z-direction (Z-axis), both axial and helical. When this option is selected, the standard CT patient couch is replaced with the patient handling system utilized by the interventional x-ray system, Toshiba INFX-8000C. The Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT will be used as part of an Aquilion PRIME / INFX-8000C based IVR-CT system. Please note, the intended uses and technological characteristics of the Aquilion PRIME CT System and the INFX-8000C Interventional X-Ray System remains the same. There have been no modifications made to the imaging chains in these FDA cleared devices and the base system software remains the same. Since both systems will be installed in the same room and to prevent interference during use, system interlocks have been incorporated into the systems.

Please note: The terms “Self-Propelled Scan Base”, “Moving Base” and “Movement Base” are used interchangeably throughout this submission. They all refer to the same unit.

12. DEVICE DESCRIPTION:

The Infinix 4DCT is composed of the INFX-8000C interventional angiography system and the dynamic volume CT system, Aquilion PRIME. This combination enables patient access and efficient workflow for interventional procedures. CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT is an optional kit intended to be used in conjunction with an Aquilion PRIME / INFX-8000C based IVR-CT system. The subject device is attached to the CT gantry to support longitudinal movement and allow image acquisition in the z-direction (Z-axis), both axial and helical. When this option is selected, the standard CT patient couch is replaced with the patient handling system utilized by the interventional x-ray system, Toshiba INFX-8000C. The intended uses and technological characteristics of the Aquilion PRIME CT System and INFX-8000C Interventional X-Ray System with which this device is used, remain the same.

13. INDICATIONS FOR USE:

Optional movable gantry base unit for use with an Aquilion PRIME system to support longitudinal movement and allow acquisition of images in the z-direction (Z-axis).

14. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to CGBA-033A, Aquilion ONE Movement Base Kit, which received premarket clearance under K134025, marketed by Toshiba America Medical Systems.

CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT, incorporates modifications to the cleared device in order for the self-propelled scan base unit to be connected to an Aquilion PRIME gantry. This allows the CT system to acquire images in the z-direction (Z-axis) when a fixed catheterization table is used for patient support instead of a dedicated CT patient couch. The indications for use, method of operation

including the imaging chain, base software and manufacturing process of the CT and Interventional XR systems remain unchanged from the cleared devices.

A complete comparison table is included in this submission. See below for a brief summary of changes from CGBA-033A, Aquilion ONE Vision Self-Propelled Base Kit:

Item	CGBA-032A, Aquilion™ PRIME Self-Propelled Scan Base Kit for IVR-CT	CGBA-033A, Aquilion™ ONE Vision Self-Propelled Scan Base Kit for IVR-CT	Comments
CT System	Aquilion™ PRIME	Aquilion™ ONE Vision	Changed
Gantry drive	Movement along rails laid on the floor	Movement along rails laid on the floor	Same
Cabling	Floor cabling	Roof cabling	Same
Couch	Fixed catheterization table (INFX-8000C System)	Fixed catheterization table (INFX-8000C System)	Same
Scan direction	IN/OUT directions	IN/OUT direction	Same
Direction of Scanogram acquisition	IN/OUT directions	IN/OUT directions	Same

The Aquilion PRIME (TSX-303A/A, 303A/B and 303A/F) received RTA Acceptance (K141741) as of July 11th, 2014. The changes made to the predicate device (K141741) include implementation of a new detector and optional software features which have been separately cleared under the 510(k) premarket notification process. CGBA-032A, Aquilion PRIME Self-Propelled Scan Base Kit for IVR-CT, is an optional kit intended to be used on an Aquilion PRIME / INFX-8000C based IVR-CT system.

15. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-4, IEC60601-1-6, IEC60601-1-9, IEC60601-2-28, IEC60601-2-32, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, IEC 60825, NEMA PS 3.1-3.18, NEMA XR-25 and NEMA XR-26. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

16. NON-CLINICAL TESTS

This submission includes summary tables detailing the risk analysis and verification/validation testing conducted through bench testing which demonstrates that the requirements for the modifications made to the system have been met. Evaluation of the modified device included, but was not limited to, confirmation that base movement speed, scanogram and axial/helical scan functions, and interlocks including contact detection, performed according to specifications.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document” issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of the modified system was conducted in accordance with the

applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems.

17. CONCLUSION

The modifications incorporated into CGBA-032A, Aquilion™ PRIME Self-Propelled Scan Base Kit for IVR-CT, do not change the indications for use or the intended use of the previously cleared devices. Based upon bench testing, successful completion of software validation, and application of risk management and design controls, it is concluded that the subject device is safe and effective for its intended use and is substantially equivalent to the predicate device.